

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
 (PCT Article 36 and Rule 70)

Applicant's or agent's file reference PP18892.002	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/01261	International filing date (day/month/year) 14 January 2003 (14.01.2003)	Priority date (day/month/year) 14 January 2002 (14.01.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/21, 45/00, 45/05, 47/00; C07K 1/00, 14/00, 17/00 and US Cl.: 530/350, 826; 424/208.1, 278.1, 282.1		
Applicant CHIRON CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:
- I Basis of the report
 - II Priority
 - III Non-establishment of report with regard to novelty, inventive step and industrial applicability
 - IV Lack of unity of invention
 - V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI Certain documents cited
 - VII Certain defects in the international application
 - VIII Certain observations on the international application

Date of submission of the demand 14 August 2003 (14.08.2003)	Date of completion of this report 14 April 2004 (14.04.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Jeffrey Stucker <i>Villa Collins for</i> Telephone No. 703-308-0196

I. Basis of the report**1. With regard to the elements of the international application:***

- the international application as originally filed.
- the description:
 pages 1-26 as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- the claims:
 pages 27-29, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- the drawings:
 pages none, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in printed form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages NONE
- the claims, Nos. NONE
- the drawings, sheets/fig NONE

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- the entire international application,
 claims Nos. 17-29

because:

- the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.
 no international search report has been established for said claims Nos. 17-29

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- the written form has not been furnished or does not comply with the standard.
 the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- restricted the claims.
 paid additional fees.
 paid additional fees under protest.
 neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- complied with.
 not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-16, in part, drawn to a composition comprising an HIV envelope antigen and LTK63.

Group II, claims 1-16, in part, drawn to a composition comprising an HIV envelope antigen and LTR72.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of the invention, LTK63, is known in the art and cannot be said to be a special technical feature. See Partidos et al. (The adjuvant effect of a non-toxic mutant of heat-labile enterotoxin of Escherichia coli for the induction of measles virus-specific CTL responses after intranasal co-immunization with a synthetic peptide, Immunology 89:483-487 (1996), cited in the international search report). Therefore, the claims do not have unity of invention.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- all parts.
 the parts relating to claims Nos. 1-16

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-16</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-16</u>	NO
Industrial Applicability (IA)	Claims <u>1-16</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-16 meet the criteria set out in PCT Article 33(2), because the prior art does not explicitly teach either LTK63 or LTR72 in combination with HIV envelope.

Claims 1-16 lack an inventive step under PCT Article 33(3) as being obvious over Neidleman et al. (*Immunology*) in view of Cohan (*Science*). Neidleman et al. teach a composition comprising either one of LTK63 or LTR72 with HIV gag protein. The reference teaches that LTK63 or LTR72 are useful mucosal adjuvants. Cohan teaches that there are several suitable HIV proteins for vaccines, including HIV envelope. See the table on page 1688. It would have been obvious to the artisan at the time the instant invention was made to combine a known adjuvant such as LTK63 or LTR72 with known immunogens with the expectation of successfully enhancing the immune response to the immunogen(s).

Claims 1-16 have industrial applicability as defined by PCT Article 33(4).

----- NEW CITATIONS -----